WEST Search History

DATE: Tuesday, May 28, 2002

Set Name side by side	Query	Hit Count	Set Name result set
DB=USPT; PLUR=YES; OP=AND			
L1	5928165	2	L1
L2	5474997	31	L2
L3	5474997.pn.	1	L3
L4	swab near10 cultur$	486	L4
L5	L4 and urethra	29	L5
L6	L5 and cotton	9	L6
L7	L6 and (male or masculine or penis or penal or distal or man)	7	L7
L8	L6 and (male or masculine or penis or penal or man)	6	L8
L9	L8 and (ph or indicator or color)	6	L9

END OF SEARCH HISTORY

WEST Search History

DATE: Tuesday, May 28, 2002

Set Name side by side	Query	Hit Count	Set Name result set
	DB=USPT; PLUR=YES; OP=AND		
L1	loop.clm. and penis.clm.	72	L1
L2	loop.clm. and penis.clm. and ph	0	L2
L3	ph.clm. and loop$.clm.	260	L3
L4	ph.clm. same loop$.clm.	50	L4
L5	(l3 or l4) and (urin$ or ureth$)	19	L5
L6	(penis or penal or urethr$) same loop$	361	L6
L7	L6 and protozoa$	1	L7
L8	L6 and (acid$ or ph)	25	L8
L9	loop same sample same ph	457	L9
L10	L9 same handle$	1	L10
L11	L9 same (device or apparatus)	46	L11
L12	sample near3 loop	3231	L12
L13	L12 same (urethra or penis or penal or urinary or vaginal)	2	L13
L14	wire near5 loop	15515	L14
L15	L14 same ph	28	L15
L16	rod near5 ph	149	L16
L17	caillouette.in.	33	L17
L18	caillouette.in. and (men or male or man or urethra or penis or penal)	12	L18

END OF SEARCH HISTORY

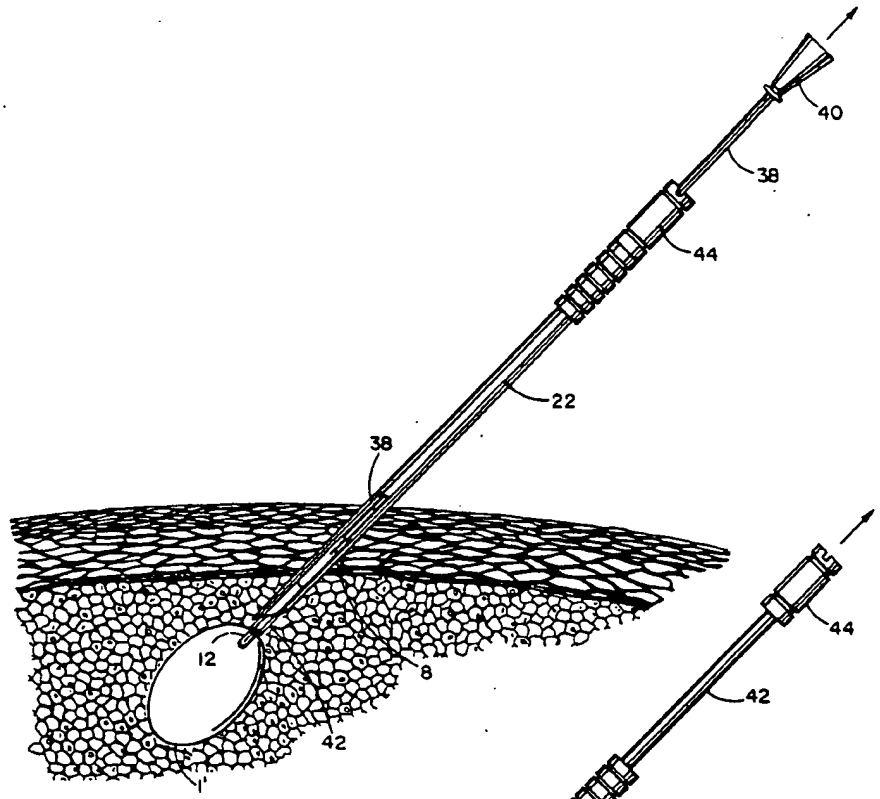

FIG. 10

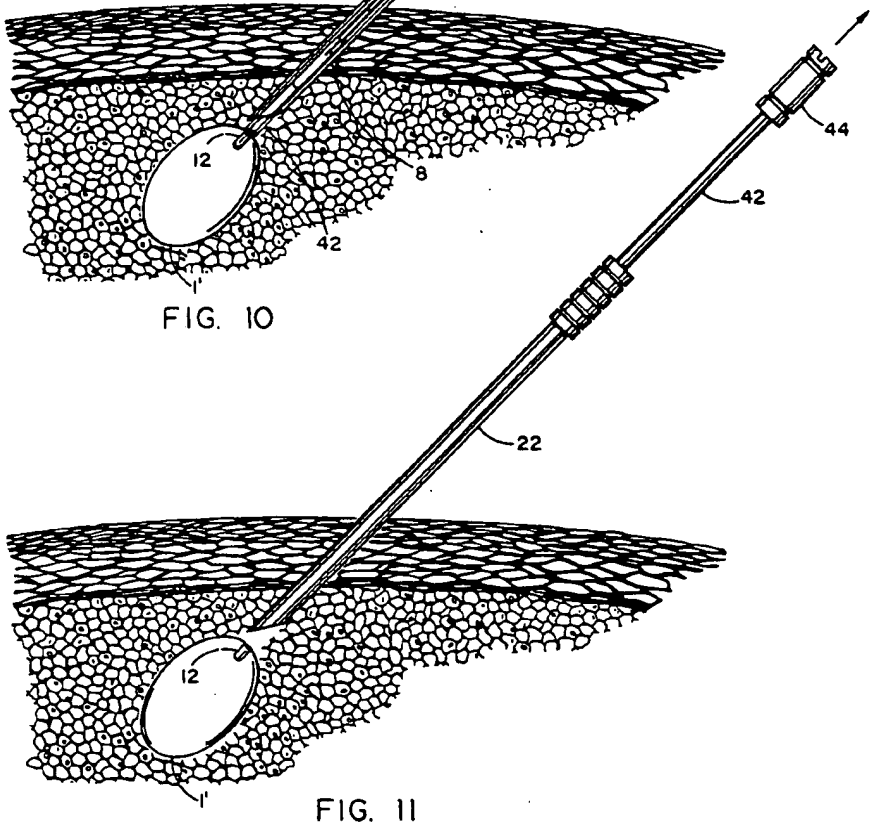

FIG. 11

WEST

Generate Collection | Print

Search Results - Record(s) 1 through 7 of 7 returned.

☐ 1. Document ID: US 5137030 A

L7: Entry 1 of 7 File: USPT Aug 11, 1992

DOCUMENT-IDENTIFIER: US 5137030 A
TITLE: Diagnostic methods

Abstract Paragraph Left (1):
A probe is provided for collecting mucous tissue samples in vivo particularly from the conjunctiva, the urethra and the cervix. The probe comprises a handle portion and a body portion, which is slotted for scraping tissue into the slots.

Brief Summary Paragraph Right (5):
It will be appreciated that both direct demonstration and culture methods require collection of a conjunctival tissue sample directly from the eye. Typically for the direct demonstration method the conjunctival sample is obtained by scraping with a sharp instrument or spatula. In the culture method the sample is obtained by the use of a cotton wool swab, and this also can sometimes be used for the direct demonstration method. In any event these procedures are uncomfortable for the patient and sometimes may not be particularly efficient.

Brief Summary Paragraph Right (7):
The direct demonstration and culture methods are also applicable to cervical or urethral tissue samples. Again cotton wool swabs have been used for obtaining such genital samples, for example mounted on a flexible wire, and these devices are expensive, and again rather inefficient.

Detailed Description Paragraph Right (5):
The urethral probe (FIG. 2) embodying the invention is similar in some respects to the ocular probe and :s described in so far as it differs therefrom: it is adapted to collect a tissue sample in vivo from the male or female urethra, and comprises a handle portion 110, intermediate portion 112 and body portion 114.

Detailed Description Paragraph Right (6):
The body portion 114 comprises a plurality of annular slots 116 again with sharp edges 120, and a nose 118 for comfortable insertion into the patients urethra. The nose 118 comprises a frusto-conical portion 119 converging into a hemispherical portion 121. The width of each slot 116 is again for example 0.25-0.5 mm. The diameter of the body portion 114 is for example 3-5 mm e.g. 4 mm. Again it is preferred to have as many slots as possible for example at least 12 more preferably at least 15; 15 slots are shown in the drawing. The axial length of the slotted region between the intermediate portion 112 and the nose 118 is for example at least 10 mm. in order to obtain a representative sample; preferably at least 14 mm. e.g. 14.25 mm.

Detailed Description Paragraph Right (31):
Samples were taken from the upper and lower lid conjunctiva of patients presenting a mild, moderate or acute conjunctivitis at the Casualty Department, Moorfields Eye Hospital London, England, using cotton wool swabs. The swabs were placed in the vials of transport medium at room temperature, and immediately prior to cytocentrifuging each vial containing the swab in the transport medium was thoroughly agitated by hand to suspend as many cells as possible in the medium while maintaining them intact. The resultant cell suspensions with the swabs removed were transferred to the cytobuckets of a Shandon Cytospin (Shandon Southern Products Limited) and cytocentrifuged directly onto slides at 1700 r.p.m. for 10 minutes. The slides were washed and rinsed; and air dried for ten minutes and the resultant monolayer smears fixed in absolute acetone for ten minutes.

CLAIMS:

10. A probe according to claim 1 adapted to collect a tissue sample from the conjunctiva or urethra wherein the width of each slot between its outer edge portions is 0.25-0.5 mm.

12. A probe according to claim 1 adapted to collect a tissue sample from the urethra or cervix wherein the body portion is cylindrical in the region of the slots and the slots are annular.

Full | Title | Citation | Front | Review | Classification | Date | Reference | Sequences | Attachments | Claims | KWIC
Draw Desc | Image

☐ 2. Document ID: US 4582699 A

L7: Entry 2 of 7 File: USPT Apr 15, 1986

DOCUMENT-IDENTIFIER: US 4582699 A
TITLE: Assay of immunoglobulin A protease and the rapid diagnosis of gonorrhea

Brief Summary Paragraph Right (13):
Biological samples which may be analyzed by the method of the present invention can be obtained via swabs, tampons or vaginal washes in the case of women and urine or penal or rectal smears in the case of men. Cultured samples of Neisseria gonorrhea from these or other biological sources may also be used. The samples may be analyzed directly or may be lyzed and/or concentrated.

Brief Summary Paragraph Right (54):
Although it is contemplated that the methods of the present invention are to be applied to biological fluids themselves, the sensitivity and specificity of the method can be improved by culture of the fluids preferably on medium selective for Neisseria gonorrhea such as Thayer-Martin, Chocolate-sugar, NYC medium or Transgro medium for 24 hours with an iron source such as Fe-dextran complex (inferon) as taught in U.S. Pat.

No. 4,229,530, prior to testing. Samples in clinical settings may be vaginal washings obtained by collecting 10 cc of PBS directed at the cervix in the case of females or may be about the first few cc of urine, in the case of males to be passed. The urine may be centrifuged and the sediment used for analysis, preferably after typing. Vaginal, urethral or rectal swabs may also be employed.

Brief Summary Paragraph Right (58):
The sample collection device, in the case of males, is a vessel marked to receive only the first few milliliters of urine to be passed. These first few milliliters wash out of the urethra the purulent discharge caused by Neisseria gonorrhea which contains the highest concentration of IgAP. An early mornng sample is preferable.

Detailed Description Paragraph Right (9):
Exudate caused by growth of N.gon. which has accumulated on the penis outside the urethral opening is collected on a cotton-tipped wooden splint.

Detailed Description Paragraph Right (23):
Male: Urine samples from males suspected of having contact with gonorrhea are prepared by centrifuging the first few milliliters of urine passed from the urethra. The supernatant solution is poured off and the remaining precipitate is suspended in 1 ml of phosphate buffered saline, 0.05M, pH 8.5.

Detailed Description Paragraph Right (33):
Fluid biological samples including a vaginal wash, urine, extract of tampon or a swab, spinal fluid, synovial fluid or a bacterial culture are suitable. The sample may be lysed before extraction of IgAP, by addition of hypertonic salts followed by adjustment of pH back to 7.5 and ionic strength of about 0.05M for optimum conditions before treating sample with antibody.

Detailed Description Paragraph Right (51):
Samples are obtained by washes or extracted from swabs or tampons in the case of females. Samples in males are the first few milliliters of urine to be voided after a period of continence. Urethral exudate may also be used. Samples may be cultured on a medium selective for Neisseria gonorrhea and harvested prior to assay. Samples may also be lyzed to release enzyme into the extra-cellular environment. For example, lysozyme from egg white (Biozyme Laboratories) prepared in 0.03M TRIS buffer, pH 9.0 is incubated with 5 ml of sample at room temperature and then centrifuged to release lyzed enzyme into the supernatant fluid.

Detailed Description Paragraph Right (55):
In the case of males, a small vial for capture of the first few milliliters of urine to be washed from the urethra after a night of continence;

Other Reference Publication (9):
Male, C. J., Infection and Immunity, vol. 26, pp. 254-261 (1979).

Full | Title | Citation | Front | Review | Classification | Date | Reference | Sequences | Attachments | Claims | KWIC | Draw Desc | Image

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☐ 3. Document ID: US 4497900 A

L7: Entry 3 of 7 File: USPT Feb 5, 1985

DOCUMENT-IDENTIFIER: US 4497900 A
TITLE: Immunoassay for Neisseria gonorrhoeae antigens

Brief Summary Paragraph Right (3):
Currently accepted procedures for the determination of gonococcal infection rely primarily upon culture techniques. Typical culture techniques include procedures described in Criteria And Techniques For The Diagnosis Of Gonorrhea, published by the Center for Disease Control, Atlanta, Ga. In such culture procedures, a specimen, i.e., a urethral or cervical sample, is placed on an acceptable culture medium, i.e., Thayer-Martin medium. The cultures are incubated at 37.degree. C. in a 5% carbon dioxide atmosphere for 24 to 48 hours. The culture plates are thereafter inspected for the appearance of Neisseria gonorrhoeae colonies. Suspect colonies are gram-stained and tested for oxidase activity. Generally, presumptive diagnosis of gonococcal infection in males is determined by obtaining urethral cultures which exhibit oxidase-positive colonies of gram-negative "coffee-bean" shaped diplococci when cultured on Thayer-Martin medium. In females, gonococcal infection may be diagnosed by examining cervical cultures on Thayer-Martin medium wherein oxidase-positive colonies of gram-negative diplococci appear. Organisms from presumptively identified colonies of Neisseria gonorrhoeae are frequently confirmed by sugar fermentation, fluorescent antibody staining or coagglutination. However such culture procedures are laborious, time-consuming and are generally limited to the detection of "living cells". When culture methods are utilized, a specimen may be taken at one location and shipped to a laboratory, usually at another location, where the organisms are cultured and identified. Thus, these culture procedures may require several days before results are obtained. Furthermore, results obtained from culture procedures may be erroneous, if, rather exacting conditions for preservation, shipment, and culturing of the bacteria are not followed.

Brief Summary Paragraph Right (12):
In accordance with the methods of the present invention, a clinical specimen is obtained from a patient suspected of having gonorrhea utilizing conventional medical and microbiological techniques. Such clinical specimens include, for example, swab specimens obtained from the cervix, urethra, throat or anus of a patient and body fluids such as synovial fluid or fluid from lesions. The clinical specimens thus obtained consists of bacterial cells containing the Neisseria gonorrhoeae antigen to be determined. In order to increase the sensitivity of the assay, it is preferred to lyse the bacteria cells to release Neisseria gonorrhoeae antigens in the specimen thereby increasing the number of antigenic sites available for binding to gonococcal antibody. Conventional techniques that may be employed to lyse the bacteria to release antigens include for example, the use of solvent dilution or high pH lysing solutions, heating, enzyme treatment, and physical agitation such as sonication and centrifugation. In a preferred embodiment of the present invention, the swab specimen is placed into a suitable lysing medium. Illustrative of suitable lysing media include, for example, phosphate buffered saline, saline and water. It is preferred to employ phosphate buffered saline. The submerged swab is rapidly twisted back and forth for about fifteen seconds or vortexed in order to release Neisseria gonorrhoeae antigens into the medium. It has unexpectedly been found that the addition of a surfactant such as sodium dodecylsulfate, Triton X-100, Tween-80 or sodium deoxycholate to the lysing medium increases the sensitivity of the method of the present invention. It has been found that the addition of deoxycholate salts, preferably sodium deoxycholate, to the lysing medium produces superior sensitivity and specificity with respect to the results obtained employing the method of the present invention.

Detailed Description Paragraph Right (14):
A strain of Neisseria gonorrhoeae, originally isolated from a patient having gonorrhea, is grown on Thayer-Martin agar in a candle extinction jar. After overnight incubation at 37.degree. C., the bacteria are

removed from the agar surface with a cotton swab. A suspension of Neisseria gonorrhoeae is made in phosphate-buffered saline 0.01M, pH 7.15, and adjusted to an optical density of 0.52 at 630 nm. This concentration is approximately equal to 10.sup.8 viable organisms per milliliter. Dilutions of the concentrated suspension are prepared in phosphate-buffered saline containing 0.1% sodium deoxycholate and are analyzed in accordance with the procedures described in Example I.

Detailed Description Paragraph Right (18):
A total of 313 urethral swabs from males and 324 endocervical swabs from females were collected at local venereal disease clinics. Soon after the swab was collected, a sample was assayed by the standard culture procedure using Thayer-Martin selective agar. The samples were also assayed in accordance with the procedures described in Example I.

Detailed Description Paragraph Right (32):
A laboratory strain of Neisseria gonorrhoeae, originally isolated from a patient having gonorrhea, is grown on Thayer-Martin agar in a candle extinction jar. After overnight incubation of 37.degree. C., the bacteria are removed from the agar surface with a cotton swab. A suspension of Neisseria gonorrhoeae bacteria is made in phosphate-buffered saline 0.01M, pH 7.15, and adjusted to an optical density of 0.52 at 630 nm. This concentration is approximately equal to 10.sup.8 viable organisms per milliliter. Dilutions of the concentrated suspension are prepared in phosphate buffered saline containing 0.1% sodium deoxycholate and were analyzed in accordance with the procedure described in Example V.

Detailed Description Paragraph Table (3):
TABLE III

Detection Results of Obtained Neisseria From Gonorrhoeae Culture Antigens % Agreement Group Number Procedure.sup.d Pos. Neg. % Sensitivity % Specificity With Culture

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Male 121 Positive 120 1 99.2 (120/121) -- 98.4 (308/313) Male 192 Negative 4 188 -- 97.9 (188/192) Female 66 Positive 59 7 89.4 (59/66) -- 94.4 (306/324) Female 258 Negative 11 247 -- 95.7 (247/258) Totals Male & 187 Positive 179 8 95.7 (179/187) -- 96.4 (614/637) Female 450 Negative 15 435 -- 96.7 (435/450)

.sup.d A culture is considered positive only if it is confirmed by sugar fermentation tests. .sup.e Results obtained using the procedure described in Example I

☐ 4. Document ID: US 4105500 A

L7: Entry 4 of 7 File: USPT Aug 8, 1978

DOCUMENT-IDENTIFIER: US 4105500 A
TITLE: Diagnostic device for a liquid sample and method

Brief Summary Paragraph Right (2):
It is frequently desirable to determine the presence of bacteria in body fluids of a patient, such as blood or urine, for purposes of diagnosis. For example, a major problem confronting hospitals today is the determination of urinary tract infections. Although chills, fever, dysuria and frequency of urination may indicate infection, the incidence of asymptomatic urinary tract infection has been shown to be a common occurence. This asymptomatic infection is clinically diagnosed by testing for bacteriuria, which literally means the presence of bacteria in the urine. Clean voided urine from normal individuals generally contains microorganisms, which are indigenous residents of the urethra. Urine in the bladder, on the other hand, is ordinarily sterile, and the presence of any bacteria in the upper urinary tract is considered abnormal. Significant bacteriuria is a term that has been used to describe the numbers of bacteria in voided urine that exceed the numbers usually due to contamination from the anterior urethra and are in the range of the bacterial titers usually found in infected bladder urine. It has been established that a guideline for determination of bladder bacteriuria is the presence of 100,000 or more bacteria per milliliter in whole voided urine, although 70 to 85% of most cases of bacteriuria are characterized by counts of over 1,000,000 organisms per milliliter.

Brief Summary Paragraph Right (13):
A further feature of the invention is that the establishing means comprises an elongated hollow member communicating with the valve means and having a swab adjacent an end distal the valve means, in order to introduce and spread a sterile suspension liquid for the sample at the sample site.

Detailed Description Paragraph Right (12):
For certain applications it is desirable to use the swab attachment 106, as shown in FIG. 8 in lieu of the needle. The attachment 106 has an elongated hollow member 108 having a passageway 110 extending longitudinally through the member 108. One end 112 of the hollow member 108 is slightly flared and may be removably attached to the outer end of the first stem 36 of the valve assembly 24, such that the passageway 110 of the hollow member 108 is in communication with the first passageway 38 of the valve assembly 24. The hollow member 108 has a swab 104, such as cotton, adjacent the other end 116 of the hollow member 108. The hollow member 108 may be used in conjunction with the device of the present invention for obtaining a sample from the site of a wound as follows. First, a liquid suspension solution, such as a saline solution, e.g., isotonic sodium chloride, is withdrawn into the syringe of the device, and ejected by the syringe to the swab and wound site, since there may not be a sufficient quantity of liquid initially present at the site to obtain an adequate sample with the device. Once the solution has been ejected against the wound site, and the solution is mixed by the swab with the sample to obtain suspension of the sample in liquid solution. Next, the solution, which contains the suspended sample, is withdrawn into the syringe and pumped into the receptacle cavity, as previously described, to inoculate the culture media.

CLAIMS:

1. A method of preparing a sample for diagnosis, comprising the steps of:

pumping a predetermined amount of sterile liquid through a swab to a sample site while the swab is located at the site;

mixing the liquid with the sample by the swab at the site for suspension of the sample in the liquid; and

aspirating the suspended sample from the sample site through the swab while the swab is located at the site after said mixing step and pumping the withdrawn sample to a culture medium without passage through the swab for inoculation of the medium.

☐ 5. Document ID: US 4018653 A

L7: Entry 5 of 7 File: USPT Apr 19, 1977

DOCUMENT-IDENTIFIER: US 4018653 A
TITLE: Instrument for the detection of Neisseria gonorrhoeae without culture

Brief Summary Paragraph Right (2):
The usual clinical evidence of a gonorrheal infection in the male is a purulent discharge from the meatus and urethra of the penis. As routine procedure it is necessary to make a differential diagnosis of the nature of the discharge before antibiotics can be prescribed. As a rule the first test is to determine if the urethritis is gonococcal or non-specific in nature. An object of this invention is therefore to provide a system which will operate directly from the patient and give the clinician or physician a differential diagnostic tool which is time saving, inexpensive and reliable.

Brief Summary Paragraph Right (3):
As a screening test for gonorrhea in public V-D clinics, hospitals, physicians' offices and the Armed Forces, the present device would serve as an inexpensive and accurate differential diagnostic aid to assist the physician or clinic in the choice of drug treatment. The need for a simple and inexpensive diagnostic system that can function in the field, independent of bacteriological and microscopic tests, is therefore well established. One of the difficulties in making a quick and reliable diagnosis of male infection is the initial confusing similarity with urethritis.

Brief Summary Paragraph Right (4):
A urethral exudate in the male may appear as a result of the following other causes: prostatitis, trauma, Escherichia coli, staphylococcus, tuberculosis, balanitis, ingested urethral irritants, cantharides, vegetables rich in oxalates, and others may precipitate urethral inflammation. Pellagra, diabetes and gout are responsible in some cases. Trichomonas vaginalis can be found in fair frequency in abacterial urethritis. Entomoeba histolytica as a cause of urethral discharge is found exclusively in the presence of recto-urethral or vesical fistula. Bilfarizia is a metozoan that produced urethritis rather frequently in endemic areas. Such systemic diseases as typhoid, mumps, influenza and smallpox can, if septicemic, produce urethritis.

Brief Summary Paragraph Right (5):
In a large percentage of individuals with acute or chronic urethral discharge, although suspected of having a gonorrheal infection, demonstration of the Neisseria is not possible. Many of these are treated as gonococcal infections and it is only when they persist, subsequent to a variety of therapeutic measures, that their abacterial nature may be recognized. Subsequent thorough examinations of the entire anterior and posterior

urethra and upper urinary tract may reveal that the signs of inflammation are present but that structural deformity is not predispositional, and, further, that etiologic organisms are totally absent.

Brief Summary Paragraph Right (8):
The principal object of this invention is to provide a diagnostic system which will detect Neisseria gonorrhea in the male without culture or the classical gram-staining method, both of which are time consuming and expensive to perform and require trained technicians and laboratory equipment.

Brief Summary Paragraph Right (9):
The present invention involves the use of a reagent from the group of oxidase testing reagents known as phenylenediamines, including the following: p-Amino Dimethylaniline Oxalate, N. N-Dimethyl-p-Phenylenediamine Dihydrochloride, N, N-Dimethyl-p-Phenylenediame Oxalate, N, N-Dimethyl-p-Phenylenediamine Monohydrochloride and N, N, N' N' Tetra-Methyl-p-Phenylenediamine Dihydrochloride. A pledget or carrier of any suitable material such as dacron fiber, cotton fiber or other porous material is impregnated or saturated with one of these reagents under certain conditions hereinafter disclosed and then dried. It remains in the dry state until it is activated by a wetting agent.

Detailed Description Paragraph Right (1):
Referring more specifically to the drawing, which represents one type of instrument capable of performing my test procedure, numeral 10 indicates a tube of transparent, flexible plastic, into which is inserted a pledget 12 of cotton impregnated or saturated with the reagent and dried. The pledget is seated on a frangible glass ampul 14 disposed in the closed end of the tube and a cap 16 is placed over the open end of the tube, sterile swab 18 with a plastic handle 20 to be used in obtaining a specimen of exudate is sealed in a separate sterile envelope 22, and the tube and envelope are packaged together in an envelope or other suitable container (not shown). While the wall structure of the plastic tube is flexible, it has sufficient rigidity normally to maintain a generally cylindrical shape and to permit easy insertion of the swab after a specimen of exudate has been taken. The ampul contains a suitable wetting agent, as described herein, and is sufficiently frangible that it can readily be broken when the sides of the flexible tube are pressed inwardly between the thumb and forefinger, whereupon the ampul shatters and permits its fluid contents to wet the material impregnated in the pledget, which normally is pushed into the fluid and fragmented glass when the swab is inserted in the tube. When the swab containing the specimen contacts the pledget, reaction between the specimen on the swab and the reagent in the pledget commences immediately and, if gonococci are present, the specimen on the swab changes color, normally to purple, red-orange, or dark gray, depending upon the reagent used in the pledget, thus indicating a positive test. The reaction time to indicate a positive specimen usually falls within the range of from 30 to 120 seconds.

Detailed Description Paragraph Right (3):
A 1% solution of N, N, N' N' Tetra Methyl-p-Phenylenediamine Di-hydrochloride is prepared as follows: 1 gram of the reagent is added to 35 ml distilled water that has been brought to a boil and allowed to cool to room temperature. Solution is effected by rapid stirring. 64 ml of Ethyl Alcohol (Fisher A-407) is then added and stirred. Strips of cotton Webril, .mu. inch wide 20 inches long, are then dipped one at a time into the solution, placed on nylon screen in a horizontal position and allowed to air-dry. The dry strips are then cut into pieces 9/16 inch long. These become the pledgets.

Detailed Description Paragraph Right (8):
To illustrate further the sensitivity of this system and its ability to detect the gonococcus precisely at the point of specimen collection on the swab, the above procedure is repeated and a culture of Neisseria gonorrheae is used as being representative of the exudate in the foregoing example. In this example the swab is used to pick a few colonies from a petri dish culture. The identical procedure is used with the instrument. A distinct purple coloration of the bacteria on the swab will be observed within one minute. The nearly colorless

pledget and the white background of the dacron swab make the identification of the organisms on the swab clear and distinct, just as it is with the exudate directly from a patient.

CLAIMS:

1. A swabbing instrument for use in the rapid detection of Neisseria gonorrhoeae without gram-staining and without culture by providing an initial distinctive color change on the swab of the instrument after collecting an inoculum on the swab, said instrument consisting essentially of:

a stick for the swab used to collect the inoculum;

a sterile swab mounted on said stick for obtaining a clinical specimen of said Neisseria from the penis as an exudate and the only inoculum of bacteria at the collection site from the patient;

a tube of transparent plastic having flexible side walls and a closed end into which the swab and inoculum are inserted by the stick;

A dry substantially colorless pledget disposed in said tube which is impregnated with a dilute colorless solution of N, N, N' N' tetramethyl-p-phenylenediamine dihydrochloride in alcohol which has been dried;

a frangible ampul containing a wetting activating agent for said tetramethyl-p-phenylenediamine compound in said tube;

said dry pledget placed above said ampul and reacting when wetted after breaking of said ampul to wet said swab without coloration but to react with Neisseria gonorrhoeae in the inoculum on said swab to produce a distinctive initial color change;

said wetting activating agent constituting the sole liquid agent to activate said dry pledget and said agent being selected from the group consisting of water, physiological saline, and aqueous buffer solutions at pH 6.5 to 7.2; and,

said initial distinctive color change being a purple shade produced on the inoculum on said swab at the site of collection of the bacteria, after said clinical specimen of exudate is taken from the patient and the swab is placed on the wetted pledget, wetted with said activating agent, and within two minutes to be directly indicative of Neisseria gonorrhoeae bacteria in said specimen.

3. A swabbing instrument for use in the rapid detection of Neisseria gonorrhoeae without gram-staining and without culture by providing an initial distinctive color change on the swab of the instrument after collecting an inoculum on the swab, said instrument consisting essentially of;

a stick for the swab used to collect the inoculum;

a sterile swab mounted on said stick for obtaining a clinical specimen of said Neisseria from the penis as an exudate and the only inoculum of bacteria at the collection site from the patient;

a tube of transparent plastic having flexible side walls and a closed end into which the swab and inoculum are inserted by the stick;

a dry substantially colorless pledget disposed in said tube which is impregnated with a dilute colorless solution in alcohol of a phenylenediamine agent selected from the group consisting of p-amino dimethylaniline oxalate,

N, N-dimethyl-p-phenylenediamine dichloride, N, N-dimethyl-p-phenylene-diamine oxalate, N, N-dimethyl-p-phenylenediamine monohydrochloride and N, N, N' N' tetramethyl-p-phenylenediamine dihydorchlide which has been dried:

a frangible ampul containing a wetting activating agent for said phenylenediamine agent in said tube;

said dry pledget placed above said ampul and reacting when wetted after breaking of said ampul to wet said swab without coloration but to react with Neisseria gonorrhoeae in the inoculum on said swab to produce a distinctive initial color change;

said wetting activating agent constituting the sole liquid agent to activate said dry pledget and said agent being selected from the group consisting of water, physiological saline, and aqueous buffer solutions at pH 6.5 to 7.2; and,

said initial distinctive color change being a purple shade produced on the inoculum on said swab at the site of collection of the bacteria, after said clinic specimen of exudate is taken from the patient and the swab is placed on the wetted pledget, wetted with said activating agent, and within two minutes to be directly indicative of Neisseria gonorrhoeae bacteria in said specimen.

☐ 6. Document ID: US 3883396 A

L7: Entry 6 of 7 File: USPT May 13, 1975

DOCUMENT-IDENTIFIER: US 3883396 A
TITLE: Gonorrhea detecting

Brief Summary Paragraph Right (3):
Despite increasingly liberal social mores regarding frank discussion of sexual contacts, sufficient social stigma remains attached to veneral diseases that many cases treated by private physicians are unreported for public health purposes and many patients are too embarrassed to even seek diagnosis in the first instance. The problem is magnified because more than 80 percent of infected women, and about 10 percent of infected men, are asymptomatic. Commonly used diagnostic methods for the disease include culturing of swab specimen samples in media, which are selective for the growth of Neisseria gonorrhoeae. A serious problem is the shoft life of the organisms outside the infected person. Specimens must be cultured promptly after sampling.

Brief Summary Paragraph Right (17):
Although pronoun references to patients are in the female gender, male patients are also contemplated and "her" or "she" includes men unless otherwise indicated.

Detailed Description Paragraph Right (6):
The antibiotic concentration (in g/l) would be 7.5 .times. 10.sup.-.sup.3 for colistin and 12.5 33 10.sup.-.sup.3 for Nystatin. The antibiotic components are tailored to the sampling site -- throat, cervix, rectum, urethra. Other inhibitors which may be employed include chelating agents such as sodium salts of ethylenediamenetetracetic acid (EDTA) to chelate heavy metal ions and calcium. Remove of calcium inactivates lysozyme which would otherwise lyse the specimen bacteria [i.e., rupture the cells].

Detailed Description Paragraph Table (2):
TABLE I _____ Holding Medium Suspended Cotton R.T. 37.degree.C Hours +P -P +P -P _____ 0 4/4 4/4 4/4 4/4 29 5/10 9/10 10/10 10/10 53.5 0/10 1/10 5/10 9/10 72.5 0/10 0/10 7/10 10/10 97.5 0/10 0/10 9/10 9/10 121.0 0/10 0/10 8/10 7/10 144.5 0/10 0/10 10/10 10/10 168.5 0/10 0/10 9/10 9/10 196.5 0/10 0/10 10/10 10/10 (7/8) (7/8) _____

Detailed Description Paragraph Table (3):
TABLE II _____ Holding Medium Suspended - 37.degree.C Charcoal Treated Cotton Rayon Cotton Hours +P -P +P -P +P -P _____ 0 4/4 4/4 6/4 4/4 4/4 4/4 45 6/6 6/7 6/7 7/7 7/7 7/7 91 6/7 6/7 4/7 7/7 6/6 6/6 140 7/7 6/7 2/7 7/7 7/7 4/7 Hours Room Temperature 0 4/4 4/4 4/4 4/4 4/4 4/4 21 5/7 6/7 6/7 7/7 1/7 1/7 45 0/7 0/7 2/7 1/7 0/7 1/7 69 0/7 0/7 -- -- -- -- 91 0/7 0/7 -- -- -- -- _____ and then by an exponential rate decaying death phase. The holding medium of the present death phase can begin as a plateau given a sufficiently high innoculum and remains substantially flat until death phase. Alternatively a low innoculum can be introduced to the medium and experience lag and growth phases until reaching a stable plateau of population level. In the layman's terms, the medium of the present invention slowly starves the bacteria with a result of stable plateau-form population curve maintenance over an extended period of time while prior media overfeed the bacteria and induce catastrophic growth and early death associated with such growth. Variations of components and concentrations and other incidental conditions of the present invention can be tested for suitability by whether they compromise stability as indicated by the observed plateau characteristic.

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DOCUMENT-IDENTIFIER: US 3876503 A
TITLE: METHOD AND INSTRUMENT FOR THE DETECTION OF NEISSERIA GONORRHEAE WITHOUT CULTURE

Brief Summary Paragraph Right (2):

The usual clinical evidence of a gonorrheal infection in the male is a purulent discharge from the meatus and urethra of the penis. As routine procedure it is necessary to make a differential diagnosis of the nature of the discharge before antibiotics can be prescribed. As a rule the first test is to determine if the urethritis is gonococcal or non-specific in nature. An object of this invention is therefore to provide a system which will operate directly from the patient and give the clinician or physician a differential diagnostic tool which is time saving, inexpensive and reliable.

Brief Summary Paragraph Right (3):
As a screening test for gonorrhea in public V-D clinics, hospitals, physicians' offices and the Armed Forces, the present device would serve as an inexpensive and accurate differential diagnostic aid to assist the physician or clinic in the choice of drug treatment. The need for a simple and inexpensive diagnostic system that can function in the field, independent of bacteriological and microscopic tests, is therefore well established. One of the difficulties in making a quick and reliable diagnosis of male infection is the initial confusing similarity with urethritis.

Brief Summary Paragraph Right (4):
A urethral exudate in the male may appear as a result of the following other causes: prostatitis, trauma, Escherichia coli, staphylococcus, tuberculosis, balanitis, ingested urethral irritants, cantharides, vegetables rich in oxalates, and others may precipitate urethral inflammation. Pellagra, diabetes and gout are responsible in some cases. Trichomonas vaginalis can be found in fair frequency in abacterial urethritis. Entomoeba histolytica as a cause of urethral discharge is found exclusively in the presence of recto-urethral or vesical fistula. Bilfarizia is a metozoan that produces urethritis rather frequently in endemic areas. Such systemic diseases as typhoid, mumps, influenza and smallpox can, if septicemic, produce urethritis.

Brief Summary Paragraph Right (5):
In a large percentage of individuals with acute or chronic urethral discharge, although suspected of having a gonorrheal infection, demonstration of the Neisseria is not possible. Many of these are treated as gonococcal infections and it is only when they persist, subsequent to a variety of therapeutic measures, that their abacterial nature may be recognized. Subsequent thorough examination of the entire anterior and posterior urethra and upper urinary tract may reveal that the signs of inflammation are present but that structural deformity is not predispositional, and, further, that etiologic organisms are totally absent.

Brief Summary Paragraph Right (8):
The principal object of this invention is to provide a diagnostic system which will detect Neisseria gonorrhea in the male without culture or the classical gram-staining method, both of which are time consuming and expensive to perform and require trained technicians and laboratory equipment.

Brief Summary Paragraph Right (9):
The present invention involves the use of a reagent from the group of oxidase testing reagents known as phenylenediamines, including the following: p-Amino Dimethylaniline Oxalate, N, N-Dimethyl-p-Phenylenediamine Dihydrochloride, N, N-Dimethyl-p-Phenylenediamine Oxalate, N, N-Dimethyl-p-Phenylenediamine Monohydrochloride and N, N, N' N' Tetra-Methyl-p-Phenylenediamine Dihydrochloride. A pledget or carrier of any suitable material such as dacron fiber, cotton fiber or other porous material is impregnated or saturated with one of these reagents under certain conditions hereinafter disclosed and then dried. It remains in the dry state until it is activated by a wetting agent.

Detailed Description Paragraph Right (1):
Referring more specifically to the drawing, which represents one type of instrument capable of performing my test procedure, numeral 10 indicates a tube of transparent, flexible plastic, into which is inserted a pledget 12 of cotton impregnated or saturated with the reagent and dried. The pledget is seated on a

frangible glass ampul 14 disposed in the closed end of the tube and a cap 16 is placed over the open end of the tube, sterile swab 18 with a plastic handle 20 to be used in obtaining a specimen of exudate is sealed in a separate sterile envelope 22, and the tube and envelope are packaged together in an envelope or other suitable container (not shown). While the wall structure of the plastic tube is flexible, it has sufficient rigidity normally to maintain a generally cylindrical shape and to permit easy insertion of the swab after a specimen of exudate has been taken. The ampul contains a suitable wetting agent, as described herein, and is sufficiently frangible that it can readily be broken when the sides of the flexible tube are pressed inwardly between the thumb and forefinger, whereupon the ampul shatters and permits its fluid contents to wet the material impregnated in the pledget, which normally is pushed into the fluid and fragmented glass when the swab is inserted in the tube. When the swab containing the specimen contacts the pledget, reaction between the specimen on the swab and the reagent in the pledget commences immediately and, if gonococci are present, the specimen on the swab changes color, normally to purple, red-orange, or dark gray, depending upon the reagent used in the pledget, thus indicating a positive test. The reaction time to indicate a positive specimen usually falls within the range of from 30 to 120 seconds.

Detailed Description Paragraph Right (3):
A 1 percent solution of N, N, N' N' Tetra Methyl-p-Phenylenediamine Di-hydrochloride is prepared as follows: 1 gram of the reagent is added to 35 ml distilled water that has been brought to a boil and allowed to cool to room temperature. Solution is effected by rapid stirring. 64 ml of Ethyl Alcohol (Fisher A-407) is then added and stirred. Strips of cotton Webril, 3/4 inch wide 20 inches long, are then dipped one at a time into the solution, placed on nylon screen in a horizontal position and allowed to air-dry. The dry strips are then cut into pieces 9/16 inch long. These become the pledgets.

Detailed Description Paragraph Right (8):
To illustrate further the sensitivity of this system and its ability to detect the gonococcus precisely at the point of specimen collection on the swab, the above procedure is repeated and a culture of Neisseria gonorrheae is used as being representative of the exudate in the foregoing example. In this example the swab is used to pick a few colonies from a petri dish culture. The identical procedure is used with the instrument. A distinct purple coloration of the bacteria on the swab will be observed within 1 minute. The nearly colorless pledget and the white background of the dacron swab make the identification of the organisms on the swab clear and distinct, just as it is with the exudate directly from a patient.

CLAIMS:

1. A method for rapid testing for Neisseria gonorrhea in the male patient without culture and without gramstaining of this organism, consisting essentially of sampling the urethral exudate of a male patient directly onto a sterile swab to thereby provide a specimen of exudate on said swab; bringing said swab into contact with a porous absorbent pledget in dry condition which has been impregnated with a sole color-forming reagent selected from the group consisting of p-Amino Dimethylaniline Oxalate, N, N-Dimethyl-p-Phenylenediamine Dihydrochloride, N, N-Dimethyl-p-Phenylenediamine Oxalate, N, N-Dimethyl-p-Phenylene diamine Monohydrochloride and N, N, N' N' Tetra-Methyl-p-Phenylenediamine Dihydrochloride, which has been placed in a tube of transparent plastic having flexible side walls and a closed end; providing a frangible ampul in said tube containing physiological salt solution at pH 6.5 to 7.2 as a wetting activating agent for reagent in said pledget which is located adjacent said pledget at the end of said tube; said impregnated pledget in the dry state being positioned above said frangible ampul and being substantially colorless before said ampul has been broken; and manually squeezing said tube at the flexible side walls near the closed end adjacent said frangible ampul to break and to release said wetting activating agent thereby wetting said pledget and swab with specimen with said liquid wetting activating agent to produce a color change on the specimen of exudate on the swab when Neisseria gonorrheae is present, the color resulting from contact between said specimen on said swab wetted by said wetting activating agent which transports

the reagent from the pledget to the swab reacting with the Neisseria gonorrheae present in the specimen and producing a color change normally to purple, red-orange or dark grey, indicating a positive test of Neisseria gonorrheae in said specimen, the fragmented material from the ampul being retained within said tube and the color being observed within 30 to 120 seconds.

3. A method for rapid testing for Neisseria Gonorrheae in the male patient without culture and without gram-staining of this organism, consisting essentially of sampling the urethral exudate of a male patient directly onto a sterile swab to thereby provide a specimen of exudate on said swab; bringing said swab into contact with a porous absorbent pledget in dry condition which has been impregnated with a sole color-forming reagent selected from the group consisting of p-Amino Dimethylaniline Oxalate, N, N-Dimethyl-p-Phenylenediamine Dihydrochloride, N, N-Dimethyl-p-Phenylenediamine Oxalate, N, N-Dimethyl-p-Phenylenediamine Monohydrochloride and N, N, N' N' Tetra-Methyl-p-Phenylenediamine Dihydrochloride, which has been placed in a tube of transparent plastic having flexible side walls and a closed end; providing a frangible ampul in said tube containing a wetting activating agent consisting of water at pH 6.5 to 7.2 which is located adjacent said pledget at the end of said tube; said impregnated pledget in the dry state being positioned in contact with said frangile ampul and being substantially colorless before said ampul has been broken; and manually squeezing said tube at the flexible side walls near the closed end adjacent said frangible ampul to break and release said water at pH 6.5 to 7.2 thereby wetting said pledget and swab with specimen to produce a color change on the specimen of exudate on the swab when Neisseria gonorrheae is present, the color resulting from contact between said specimen on said swab wetted by water which transports the reagent from the pledget to the swab reacting with the Neisseria gonorrheae present in the specimen and producing a color change normally to purple, red-orange or dark grey, indicating a positive test of Neisseria gonorrheae in said specimen, the fragmented material from the ampul being retained within said tube and the color being observed within 30 to 120 seconds.